



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,842	07/10/2007	Yusuke Nakamura	082368-000510US	3233
20350 7590 10/30/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834				
EXAMINER				
HALVORSON, MARK				
ART UNIT		PAPER NUMBER		
1642				
MAIL DATE		DELIVERY MODE		
10/30/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/593,842

**Applicant(s)**

NAKAMURA ET AL.

**Examiner**

Mark Halvorson

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### DETAILED ACTION

Claims 1-68 are pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7, drawn to a method of diagnosing non-small cell lung cancer (NSCLC) or a predisposition to developing non-small cell lung cancer in a subject, comprising determining the expression level of a non-small cell lung cancer-associated gene in a biological sample derived from the subject, wherein an increase of said expression level compared to a normal control level of said gene indicates that said subject suffers from or is at risk of developing NSCLC, wherein said NSCLC-associated gene is selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1

Group 2, claim(s) 8, drawn to a NSCLC reference expression profile, comprising a gene expression pattern of two or more genes selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1

Group 3, claim(s) 9 and 10, drawn to a kit comprising two or more detection reagents which detect the expression of one or more genes selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1.

Group 4, claim(s) 11-12, 16, 17 drawn to a method of identifying a compound that inhibits the expression level of an NSCLC-associated gene, comprising the steps of:(1) contacting a test cell expressing said NSCLC-associated gene with a test compound;(2) detecting the expression level of said NSCLC-associated gene; and(3) determining the compound that suppresses said expression level compared to a normal control level of said gene as an inhibitor of said NSCLC-associated gene wherein said NSCLC-associated gene is selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1.

Group 5, claim(s) 13, drawn to a method of screening for a compound for treating or preventing NSCLC, said method comprising the steps of:(1) contacting a test compound with a polypeptide selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1;(2) detecting the binding activity between the polypeptide and the test compound; and(3) selecting a compound that binds to the polypeptide.

Group 6, claim(s) 14 and 15, drawn to a method of screening for a compound for treating or preventing NSCLC, said method comprising the steps of:(a) contacting a test compound with a polypeptide encoded by a polynucleotide selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1;(b) detecting the biological activity of the polypeptide of step (a); and(c) selecting a compound that suppresses the biological activity of the polypeptide selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1 in comparison with the biological activity detected in the absence of the test compound.

Group 7, claim(s) 18, drawn to a method of screening for compound for treating or preventing NSCLC, said method comprising the steps of:(1) contacting a test compound with a cell into which a vector comprising the transcriptional regulatory region of one or more marker genes and a reporter gene that is expressed under the control of the transcriptional regulatory region has been introduced, wherein the one or more marker genes are selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1;(2) measuring the activity of said reporter gene; and(3) selecting a compound that reduces the expression level of said reporter gene, as compared to a control.

Group 8, claim(s) 19-21, drawn to a method of screening for a compound for treating or preventing NSCLC, said method comprising the steps of:(1) contacting a KIF11 polypeptide or functional equivalent thereof with KOC1 polypeptide or functional equivalent thereof in the presence of a test compound;(2) detecting the binding between the polypeptides; and(3) selecting the test compound that inhibits the binding between the polypeptides.

Group 9, claim(s) 22-24, drawn to a method of measuring RNA transporting activity of a polypeptide.

Group 10, claim(s) 25, drawn to a method identifying an agent that modulate RNA transporting activity.

Group 11, claim(s) 26-27, drawn to a method of screening for a compound for treating or preventing NSCLC, said method comprising the steps of:(1) contacting a KOC1 polypeptide, or functional equivalent thereof with a RNA in the presence of a test compound;(2) detecting the binding between the polypeptide and RNA; and(3) selecting the test compound that inhibits the binding between the polypeptide and RNA.

Group 12, claim(s) 28-30, drawn to a method of screening for a compound for treating or preventing NSCLC, said method comprising the steps of:(1) contacting a GHSR1b or NTSR1 polypeptide, or functional equivalent thereof with NMU in the existence of a test compound;(2) detecting the binding between the polypeptide and NMU; and(3) selecting the test compound that inhibits the binding between the polypeptide and NMU.

Group 13, claim(s) 31, drawn to a kit for detecting for an activity of a test compound to regulate RNA transporting activity, said kit comprising an isolated cell expressing the following components of a to d, and culture medium supporting the cell growth: a. a polypeptide selected from the group consisting of a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 ;b. a polypeptide selected from the group consisting of: a polypeptide comprising the amino acid sequence of SEQ ID NO: 105 (KOC1);;c. a RNA to be transported; and DCTN1..

Group 14, claim(s) 32 and 33 drawn to a kit for screening for a compound for treating or preventing NSCLC, comprising at least following elements: a. a polypeptide selected from the group consisting of a polypeptide comprising the amino acid sequence of SEQ ID NO: 105 (KOC1) and a RNA binding with said polypeptide.,

Group 15, claim(s) 34, drawn to a kit for screening for a compound for treating or preventing NSCLC, comprising: GHSR1b or NTSR1 polypeptide, NMU, and reagent for detecting the binding between the polypeptide and NMU.

Group 16, claim(s) 35, drawn to a method of treating or preventing NSCLC in a subject comprising administering to said subject an antisense composition, said composition comprising a nucleotide sequence complementary to a coding sequence of a gene selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1.

Group 17, claim(s) 36-38, drawn to a method of treating or preventing NSCLC in a subject comprising administering to said subject an siRNA composition comprising an siRNA, wherein said composition reduces the expression of a gene selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1.

**Additionally, Applicants are required under 35 U.S.C. 121 to elect a single siRNA nucleotide sequence from the group consisting of SEQ ID NO:32, 33, 34, 35, 36, 37 and 108 because each sequence presents a structurally and functionally distinct invention not a species. Applicant are reminded that any claims not reading on the elected sequence(s) will be withdrawn as being drawn to a non-elected invention.**

Group 18, claim(s) 39, drawn to a method for treating or preventing NSCLC in a subject comprising the step of administering to said subject a pharmaceutically effective amount of an antibody that binds to a polypeptide encoded by a gene selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1.

Group 19, claim(s) 40, drawn to A method of treating or preventing NSCLC in a subject comprising administering to said subject a vaccine comprising a polypeptide encoded by a gene selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1 or an immunologically active fragment of said polypeptide or a polynucleotide encoding a polypeptide selected from the group consisting of KIF11, GHSR1b, NTSR1, and FOXM1.

Group 20, claim(s) 41, drawn to a method for treating or preventing NSCLC in a subject, said method comprising the step of administering a compound that is obtained by the method according to any one of claims 13 to 23, and 28 to 34, or the agent that is identified by the method according to claim 27..

Group 21, claim(s) 42 and 43 drawn to a method for treating or preventing NSCLC in a subject, said method comprising the step of administering a KOC1 mutant having dominant negative effect or a polynucleotide encoding a KOC1 mutant having dominant negative effect.

Group 22, claim(s) 44-61, drawn to a double stranded polynucleotide and vector comprising the polynucleotide.

**Additionally, Applicants are required under 35 U.S.C. 121 to elect a single siRNA nucleotide sequence from the group consisting of SEQ ID NO:32, 33, 34, 35, 36, 37 and 108 because each sequence presents a structurally and functionally distinct invention not a species. Applicant are reminded that any claims not reading on the elected sequence(s) will be withdrawn as being drawn to a non-elected invention.**

Group 23, claim(s) 62, drawn to a composition comprising an antibody.

Group 24, claim(s) 63, drawn to a composition for treating or preventing NSCLC, said composition comprising a pharmaceutically effective amount of the compound selected by the method of any one of claims 13 to 23, and 28 to 34, or the agent that is identified by the method according to claim 27 as an active ingredient, and a pharmaceutically acceptable carrier..

Group 25, claim(s) 64 and 65, drawn to a composition for treating or preventing NSCLC, said composition comprising a pharmaceutically effective amount of the KOC1 mutant having dominant negative effect, or a polynucleotide encoding the mutant as an active ingredient, and a pharmaceutically acceptable carrier.

Group 26, claim(s) 66 and 67, drawn to a method of predicting a NSCLC prognosis, wherein the method comprises the steps of: a. detecting expressing level of either or both of KIF11 and KOC1 in a specimen collected from a subject whose NSCLC prognosis is to be predicted, and b. indicating a poor prognosis when an elevation of the expressing level of either or both of KIF11 and KOC1 is detected

Group 27, claim(s) 68, drawn to a kit for predicting a NSCLC prognosis, wherein the kit comprising any one component select from the group consisting of:(a) reagent for

Art Unit: 1642

detecting the mRNA encoding the amino acid sequence of SEQ ID NO: 2 (KIF11) or SEQ ID NO: 105 (KOC1), (b) reagent for detecting the protein comprising the amino acid sequence of SEQ ID NO: 2 (KIF11) or SEQ ID NO: 105 (KOC1), and (c) reagent for detecting the biological activity of the protein comprising the amino acid sequence of SEQ ID NO: 2 (KIF11) or SEQ ID NO: 105 (KOC1)

**Further Restriction Requirement**

The claims are drawn to methods which require identifying one or more NSCLC associated genes or one or more NSCLC associated proteins. The NSCLC associated genes are KIF11, GHSR1b, NTSR1 and FOXM1 which are separate and distinct genes. Thus, the claims are directed to numerous distinct methods recited in the alternative. The language "one or more NSCLC associated genes or one or more NSCLC associated proteins" requires that one, two, three or four NSCLC associated genes in a sample or one, two, three or four NSCLC associated proteins in a sample. For example, a method requiring the KIF11 protein is distinct from a method requiring the GHSR1b protein because the methods have a different mode of operation, do not overlap in scope, and they are not obvious variants of one another (see MPEP 806.05(j)). The NSCLC associated proteins consist of distinct sequences. Furthermore, the language "one or more NSCLC associated genes" requires that one, two, three or any number more up to the numerous LCAT nucleic acids in a sample. For example, a method requiring a nucleic acid probe corresponding to the NSCLC associated gene, KIF11 is distinct from a method requiring the NSCLC associated gene, GHSR1b because the methods have a different mode of operation, do not overlap in scope, and they are not obvious variants of one another (see MPEP 806.05(j)). The LCAT nucleic acids consist of distinct sequences.

The claims further encompass many subcombinations which are disclosed as usable together in a single combination and which are also separately usable. For example, consider the following combinations of "a plurality of NSCLC associated proteins from the group consisting KIF11, GHSR1b, NTSR1 and FOXM1.

Subcombination (A): the marker gene within the group consisting of  
KIF11 and GHSR1b



Subcombination (B): the within the group consisting of NTSR1 and FOXM1

Combination (A+B): the within the group consisting of KIF11, GHSR1b, NTSR1 and FOXM1.

Each of the combinations of NSCLC associated proteins and NSCLC associated nucleic acids are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In this case subcombinations (A) and (B) do not overlap in scope and there is no evidence on the record to suggest that they are obvious variants of one another. The subcombinations are separately usable as evidenced by their presentation in the alternative within the claims. Further, subcombination "A" has separate utility such as detecting the NSCLC associated protein or NSCLC associated nucleic acid, as a marker, or for linkage studies, for examples . So, subcombinations (A) and (B) are distinct. See MPEP § 806.05(d).

These subcombinations are also distinct from the combination which comprises them because the combination does not require the particulars of the subcombination as claimed to show novelty or unobviousness and the subcombinations have utility by themselves or in another combination. The fact that the claim encompasses an embodiment which relies on only subcombination (B) is evidence that the details of subcombination (A) are not required for patentability of the combination (A+B), and likewise, the fact that the claim encompasses an embodiment which relies on only subcombination (A) is evidence that the details of subcombination (B) are not required for patentability of subcombination (A+B). The fact that the claim encompasses embodiments which use only subcombination (A) or subcombination (B) is evidence that the subcombinations have utility by themselves.

This example particularly discusses only the combinations (A), (B) and (A+B), but the same analysis could be applied to each of the different subcombinations and combinations set forth in the instant claims.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Each NSCLC associated protein or NSCLC associated nucleic acid must be searched by a separate query of the electronic databases. See MPEP 808.02(C). Therefore, a search for methods which use each combination of NSCLC associated proteins or NSCLC associated nucleic acids is not co-extensive with methods which use each other combination of NSCLC associated proteins or NSCLC associated nucleic acids, and subsequently, the search and examination for every combination of NSCLC associated proteins or NSCLC associated nucleic acids poses an enormous and serious burden on the examiner.

**Applicant is required to select a single invention, ie, a single combination of NSCLC associated proteins or NSCLC associated nucleic acids required for the claimed methods.** For Inventions 1-27, the invention may be one NSCLC associated proteins or combination of more than two NSCLC associated proteins. The Invention may be one NSCLC associated nucleic acids or combination of more than one NSCLC associated proteins. However, an election of a single combination of NSCLC associated proteins or NSCLC associated nucleic acids is required. This restriction requirement is predicated on the fact that the methods which use different NSCLC associated proteins or NSCLC associated nucleic acids or different combinations of NSCLC associated proteins or NSCLC associated nucleic acids do not appear obvious over one another. Should applicant traverse on the ground that the different NSCLC associated proteins or NSCLC associated nucleic acids or different combinations of NSCLC associated proteins or NSCLC associated nucleic acids are not patentably distinct over each other, applicant should submit evident or identify such evidence now of record showing the inventions to be obvious variant over each other or

clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding, special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c), 37 C.F.R. 1.475(d)

The invention listed as Groups 1-27 do not relate to a single inventive concept under PCT Rule 1.31 because, under PCT 13.2 they lack the same or corresponding special technical feature for the following reasons:

The technical feature of claim 59 is a composition comprising an antisense polynucleotide against a gene selected from the group consisting of KIF11, GHSR1b, NTSR1 or FOXM1.

Wonsey et al (US Patent Application Publication 2006/0014686, published Jan 19, 2006, filed Feb 6, 2004) describes antisense oligonucleotides to FOXM1 and

methods for screening for agents that modulate the expression or activity of FOXM1). (claims 1-4 and 7-10). Thus, the claim 59 lacks a special technical feature.

Thus, the different groups in the present application do not contain a single inventive concept and puts a serious search burden on the Examiner.

### ***SPECIES ELECTION***

This application contains claims directed to the following patentably distinct species of the claimed invention. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

(i). **Groups 19 and 21** are subject to election of at least one of the disclosed species.

Claims 40 and 42 are generic to a plurality of disclosed patentably distinct species of compounds whereby the compounds are selected from the group consisting of: **a polypeptide or the polynucleotide encoding a polypeptide**. The species are independent or distinct because they are functionally and structurally different molecules.

(ii). **Group 22** is subject to election of at least one of the disclosed species.

Claims 59 and 60 are generic to a plurality of disclosed patentably distinct species of polynucleotides whereby the polynucleotides are selected from the group consisting of: **antisense polynucleotides and siRNA**. The species are independent or distinct because they are functionally and structurally different molecules.

(iii). **Group 24** is subject to election of at least one of the disclosed species of compositions.

Claim 63 is generic to a plurality of disclosed patentably distinct species of

compositions using the methods of Groups 5-9 and 12 whereby the compositions are selected from the methods consisting of : **Groups 5, 6, 7, 8, 9 and 12**. The species are independent or distinct because they are identified using distinct methods.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Examination will begin with the elected species. As per MPEP 803.02, if the elected species is found to be unpatentable, the provisional election will be given effect and all other claims to species will be withdrawn from consideration. If the elected species is found to be allowable, the search will be expanded by the Examiner to consider additional species and subgeneruses within the generic formula until:

- I. An art rejection can be made.
- II. The genus claim is found to lack unity of invention.
- III. The claims have been searched in their entirety.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1)

share a common utility, and (2) share a substantial structural feature essential to that utility.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Mark Halvorson/  
Examiner, Art Unit 1642